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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,468	03/17/2004	Peter J. Fitzgerald	DYRX-001	5475
24353	7590	09/01/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			AHMED, AAMER S	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/803,468	FITZGERALD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10,22-27,43-52 and 66 is/are pending in the application.
- 4a) Of the above claim(s) 11-21,28-42,53-65 and 67-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,22-27,43-52 and 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>06/16/04, 10/07/04</u>  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 22, 26, 27, 43, 45, 47, 49, 50, 52 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Aigner U.S. Patent Number 4,666,426. Aigner ('426) describes a method of removing an agent from a physiological efferent fluid collection site, the method comprising of introducing a non-occlusive aspiration element (10) to a target site at least proximal to said physiological efferent fluid collection site; and activating the aspiration element when the agent is at least predicted to be present in the target site to selectively remove the agent from the site; and wherein the collection site is a coronary sinus of a human (col. 3 line 25). Furthermore, Aigner ('426) describes a system (see figure 4) including a non-occlusive aspiration lumen (13); an aspiration mechanism operatively connective to the lumen (10), an actuation controller element (2) for controlling actuation of the aspiration mechanism (10) and a detector for at least predicting the presence of the agent (4) see figure 4. Moreover, Aigner ('426) discloses that the aspiration lumen (13) is present in an elongated tubular structure (14). Moreover, Aigner ('426) discloses a device (10) for selectively removing an agent from a physiological efferent fluid collection site, a non-occlusive aspiration lumen (13) present in an elongated tubular structure (14) having a fenestrated distal end (11); an aspiration mechanism (10) operatively connected to the non-occlusive aspiration lumen (13); and an actuation controller element (2) for controlling

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actuation of the aspiration element; and wherein the elongated tubular structure (14) comprises a non-expandable distal end (12) and comprises non-sealable fenestrae (11) and an open distal end (12) see figure 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-10 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aigner ('426) in view of Movahed U.S. Patent Application 2002/0099254. Aigner discloses a method of removing an agent from a physiological efferent fluid collection site as described above in reference to claim 1, furthermore Aigner describes a system for selectively removing an agent from a physiological efferent fluid collection site as described above in reference to claim 22. Aigner fails to disclose that the agent is a therapeutic agent, or a diagnostic contrast agent, nor that the system comprises a feedback element, that the actuation controller selectively

actuates in response to signals from the feedback element, that the controller element is an adaptive controller element.

Movahed ('254) discloses a similar method, system and device, which describe removal of a therapeutic agent, a diagnostic agent, and a contrast agent (p.2 paragraph 19). Moreover, Movahed ('254) discloses that the system comprises a feedback element that the actuation controller selectively actuates in response to signals from the feedback element that the controller element is an adaptive controller element (p. 4 paragraph 57). It would have been obvious to one having ordinary skill in the art at the time of the invention by applicant to modify the method and system of Aigner ('426) by incorporating the removal of therapeutic, diagnostic or contract agents as well as incorporating a feedback element as taught by Movahed ('254) in order to prevent the agent from entering the circulatory system (p. 4 paragraph 60).

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aigner ('426) in view of Alley et al U.S. Patent Number 3,903,895. Aigner ('426) discloses the aspirating device as described above in reference to claim 43. Aigner ('426) fails to disclose a positioning or a retaining element.

Alley et al ('895) discloses a similar device including a retaining element (114), see figure 6. It would have been obvious to one having ordinary skill in the art at the time of the invention by applicant to modify the device of Aigner ('426) by adding the retaining element as taught by Alley et al ('895) in order to help in clamping the catheter in position with respect to the heart (col. 1 line 44).

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aigner ('426) in view of Stevens et al U.S. Patent Application Number 2003/0040736. Aigner ('426) discloses

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the aspirating device as described above in reference to claim 43. Aigner ('426) fails to disclose an expandable distal end.

Stevens et al ('736) discloses a similar device including an expandable distal tip (See Figure 4G). It would have been obvious to one having ordinary skill in the art at the time of the invention by applicant to modify the device of Aigner ('426) by adding an expandable distal tip as taught by Stevens et al ('736) in order to vent blood (p2. paragraph 15).

Claims 46, 48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aigner ('426) in view of Nichols et al U.S. Patent Number 4,753,640. Aigner ('426) discloses the aspirating device as described above in reference to claim 43. Aigner ('426) fails to disclose both sealable and non-sealable distal fenestrae.

Nichols et al ('640) discloses a similar device, which includes sealable and non-sealable fenestrae (col. 6 line 9). It would have been obvious to one having ordinary skill in the art at the time of the invention by applicant to modify the device of Aigner ('426) by adding the sealable and non-sealable fenestrae as taught by Nichols et al ('640) in order to serve to raise the withdrawal threshold, providing for a more positive, highly reliable valve action (Nichols et al '640 col. 6 line 43).

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5527292 A	Adams; Daniel O. et al.
US 4648865 A	Aigner; Karl
US 4563170 A	Aigner; Karl
US 5827229 A	Auth; David C. et al.
US 20020035347 A1	Bagaoisan, Celso J. et al.
US 20020177800 A1	Bagaoisan, Celso J. et al.

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US 6398773 B1	Bagaoisan; Celso J. et al.
US 6849068 B1	Bagaoisan; Celso J. et al.
US 20030195536 A1	Bashiri, Mehran et al.
US 5984892 A	Bedingham; William
US 4759349 A	Betz; Bard B. et al.
US 4240433 A	Bordow; Richard A.
US 5441482 A	Clague; Cynthia T. et al.
US 6562020 B1	Constantz; Brent R. et al.
US 3963028 A	Cooley; Denton A. et al.
US 5358507 A	Daily; Pat O.
US 5522826 A	Daily; Pat O.
US 5588952 A	Dandolu; Bhaktavathsala R.
US 4228798 A	Deaton; David W.
US 5419769 A	Devlin; Thomas et al.
US 20050027236 A1	Douk, Nareak
US 3623483 A	Dyer, Jr.; Richard H.
US 5656027 A	Ellingboe; Bruce S.
US 5009634 A	Feldman; Marc D. et al.
US 5728151 A	Garrison; Michi E. et al.
US 5928218 A	Gelbfish; Gary A.
US 5938645 A	Gordon; Lucas S.
US 20040116902 A1	Grossman, Phillip et al.
US 6406471 B1	Jang; Yue-Teh et al.
US 6723085 B2	Jang; Yue-Teh et al.
US 20050159716 A1	Kobayashi, Susumu et al.
US 5328459 A	Laghi; Aldo A.
US 5554136 A	Luther; Ronald B.
US 4838855 A	Lynn; Lawrence A.
US 5531672 A	Lynn; Lawrence A.
WO 2058777 A2	MOVAHED, M REZA
US 6468262 B1	Murphy; Richard O.
US 4180074 A	Murry; Edward J. et al.
US 5827243 A	Palestrant; Aubrey M.
US 5123903 A	Quaid; Joel K. et al.
US 6001078 A	Reekers; Jan Albertus
US 5476450 A	Ruggio; Joseph M.
US 6322513 B1	Schregel; Werner
US 4068664 A	Sharp; Russell G. et al.
US 6364847 B1	Shulze; John E. et al.
US 20010044591 A1	Stevens, John H. et al.
US 5916193 A	Stevens; John H. et al.
US 5902264 A	Toso; Kenneth E. et al.
US 4705501 A	Wigness; Bruce D. et al.
US 5336176 A	Yoon; InBae

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US 6565535 B2


Zaias; Nardo et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.A.

  
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